

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re F	Patent Application of:	)	Group Art Unit: 1645
	Paula J. BATES	)	Examiner:
Applic	eation No. 10/607,455	)	
Filed:	June 26, 2003	)	
For:	A Method for the Detection of Apoptosis	) ) )	
P.O. B	issioner for Patents ox 1450 dria, VA 22313-1450		•

## TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT WITHIN THREE MONTHS OF FILING OR BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. section 1.97(b))

### IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

Cite numbers 27 (Martelli) and 34 (Rosenthal) were cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1). A copy of the International Search Report, mailed on November 13, 2003, is enclosed.

Transmittal of Information Disclosure Statement Page 2

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Respectfully submitted,

Dated: // FEB DY

Bv:

David E. Crawford, Jr., Reg. No. 38,11

Customer No. 26263 314.259.5810

23131549\V-1



PTO/SB/08a (08-03) Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of info unless it contains a valid OMB control number.

substitute for form 1449A/PTO

### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

 Complete if Known

 Application Number
 10/607,455

 Filing Date
 June 26, 2003

 First Named Inventor
 Paula J. Bates

 Group Art Unit
 1645

 Examiner Name
 09799910-0034

(use as many sheets as necessary)
Sheet 1 of 4

U.S. PATENT DOCUMENTS Pages, Columns, Lines, Document Number Examiner Cite **Publication Date** Name of Patentee or Where Relevant Passages or No.1 MM-DD-YYYY Applicant of Cited Document Initials1 Number-Kind Code<sup>2 (if known)</sup> Relevant Figures Appear 1 US-5,925,334 07-20-1999 Rubin et al. 2 US-5,932,475 08-03-1999 Bandman et al. 3 US-6,048,703 04-11-2000 Siman et al. 4 US-6,291,643 09-18-2001 Zou et al. 5 US-6,325,785 12-04-2001 Babkes et al. 6 US-6,339,075 01-15-2002 King et al.

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Foreign Patent Number  Country Code <sup>3</sup> Number Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Le		
	7	WO 00/61597	10-19-2000	UAB Research Foundation				
Examiner Signature				Date Considered				

23131546\V-1

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unquie citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file ( and by the USPTO to process) an application. Confidentiallily is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of info unless it contains a valid OMB control no.

oe a plus sign (+) inside this box ™

Substitu	te for fo	orm 1449B/PTO	Complete if Known					
			Application Number 10/607,455		•			
		ATION DISCLOSURE	Filing Date	June 26, 2003				
STA	ГЕМІ	ENT BY APPLICANT	First Named Inventor	Paula J. Bates				
			Group Art Unit	1645				
	(	use as many sheets as necessary)	Examiner Name					
Sheet		2 of 4	Attorney Docket No.	09799910-0034				
		OTHER ITEMS - NON PATE	NT LITERATURE DOCUME	NTS				
Examiner Initials*	Cite No.1	item (book, magazine, journal, serial, syn	L LETTERS), title of the article (when appropriate), title of the mposium, catalog, etc.), date, page(s), volume-issue number(s), ty and/or country where published.					
	8	BATES et al., "Antiproliferative Act Protein Binding," J. Biol. Chem., 19	999, pp. 26369-26377, Vol	. 274.				
	9	BISCOTTI et al., "Apoptotic Bodies Endocervical Adenocarcinoma in s 22.	situ," Am. J. Surg. Pathol.,	1998, pp. 434-439, Vol.				
,	10 CALLEBAUT et al., "Identification of V3 Loop-binding Proteins as Potential Receptors Implicated in the Binding of HIV Particles to CD4+ Cells," Biol. Che 1998, pp. 21988-21997, Vol. 273.							
	11	CHOI et al., "Apoptosis and Nuclear Shapes in Benign Prostate Hyperplasia and Prostate Adenocarcinoma: Comparison with and Relation to Gleason Score," Int. J. Urol., 1999, 13-18, Vol. 6.						
	12	COQUERET et al., "Functional Interaction of STAT3 Transcription Factor with the Cell Cycle Inhibitor p21 <sup>WAF1/CIP1/SDI1</sup> ," J. Biol. Chem., 2000, pp. 18794-18800, Vol. 275.						
	13	DAVIS et al., Staining of Cell Surface Human CD4 with 2'-F-pyrimidine-containing RNA Adptamers for Flow Cytometry," Nucl. Acids Res., 1998, pp. 3915-3924, Vol. 26.						
	14	DERENZINI, "The AgNORs." Micron., 2000, pp. 117-120, Vol. 31.						
	15 FACOMPRE et al., "Apoptotic Response of HL-60 Human Leukemia Cells to the Antitumor Drug NB-506, a Glycosylated Indolocarbazole Inhibitor of Topoisomeras 1," Biochem. Pharmacol., 2001, pp. 299-310, Vol. 61.							
	16	GAUTIER et al., "Production and Characterisation of a Monoclonal Antibody Specific for Apoptotic Bodies Derived from Several Tumour Cell Lines," J. Immunol. Methods., 1999, pp. 49-58, Vol. 228.  GAVRIELI et al., "Identification of Programmed Cell Death in situ Via Specific Labeling of Nuclear DNA Fragmentation," J. Cell Biol., 1992, pp. 493-501, Vol. 119.						
	17							
	18	GINISTRY et al., "Structure and Functions of Nucleolin," J. Cell Sci., 1999, pp. 761-772, Vol. 112.						
	19	HOLDENRIEDER et al., "Nucleo Malignant Diseases," Int. J. Cance	r, 2001, pp. 114-120, Vol.	95.				
	20	HOLDENRIEDER et al., "Circulatir 2001, pp. 93-102, Vol. 945.						
	21 HOLDENRIEDER et al., "Nucleosomes in Serum as a Marker for Cell Death," Clin. Chem. Lab. Med., 2001, pp. 596-605, Vol. 39.							

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

<sup>1</sup> Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

# stitute for form 1449B/PTO

**INFORMATION DISCLOSURE** STATEMENT BY APPLICANT

Complete if Known 10/607,455 Application Number June 26, 2003 Filing Date Paula J. Bates First Named Inventor 1645 **Group Art Unit** Examiner Name

(use as many sheets as necessary)

Sheet	3	of	4	Attorney Docket No.	09799910-0034

Sheet		3	of	4		Attorney Docket No.	09799910-0034	
	OTHER ITEMS – NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No. Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.							T <sup>2</sup>
	22	KERR et al., "Apoptosis: A Basic Biological Phenomenon with Wide-Ranging Implications in Tissue Kinetics," Br. J. Cancer, 1972, pp. 239-257, Vol. 26.						
	23	KIM et al., "A Micro Double Capillary Method for Rheologic Measurements of Lower Airway Secretions," Bull Eur. Physiopathol. Respir., 1982, pp. 915-927, Vol. 18.						
	24	LANGER et al., "Enzymatic Synthesis of Biotin-Llabeled Polynucleotides: Novel Nucleic Acid Affinity Probes," Proc. Natl. Acad. Sci. USA., 1981, pp. 6633-6637, Vol. 78.						
	25	Cell. Bioch	nem.,	1993, pp. 153-1	158	tion of Nucleolar Proteins in , Vol. 52.		
	26	Sci., 2001	, pp.	239-249, Vol. 94	15.	Nucleic Acids and Apopto		
	27	Matrix fror	n Ap	optotic HL-60 Ce	ells	d Morphological Character ," J. Cell. Biochem., 1999,	pp. 35-46, Vol. 72.	
	28	MARTIN et al., "Protease Activation During Apoptosis: Death by a Thousand Cuts?," Cell, 1995, pp. 349-52, Vol. 82.						
	29	MCNICOL et al., "Optimizing Immunohistochemistry: Antigen Retrieval and Signal Amplification, "Histopathology, 1998, pp. 97-103, Vol. 32.						
	30							
	31	ORFAO et al., "General Concepts About Cell Sorting Techniques," Clin. Biochem., 1996, pp. 5-9, Vol. 29.						
	32							
	33							
	34	ROSENTHAL et al., "Detection of DNA Breaks in Apoptotic Cells Utilizing the DNA Binding Domain of poly(ADP-ribose) Polymerase with Fluorescence Microscopy," Nucl. Acids Res., 1997, pp. 1437-1441, Vol. 25.						
	35	SCHIMMER et al., "Receptor- and Mitochondrial-Mediated Apoptosis in Acute Leukemia: A Translational View," Blood, 2001, pp. 3541-3553, Vol. 98.						
	36	Bodies Inc 15.	luced	by Antinuclear	An	Cells' Result from Phagocyt tibodies," J. Autoimmun., 2	000, pp. 15-20, Vol.	
	37	1999, pp.	125-	137, Vol. 199.		sylation) and Apoptosis," M		
	38							

FEB 1 7 2004 Cubstill

Complete if Known Substitute for form 1449B/PTO 10/607.455 Application Number INFORMATION DISCLOSURE June 26, 2003 Filing Date STATEMENT BY APPLICANT Paula J. Bates First Named Inventor 1645 Group Art Unit (use as many sheets as necessary) **Examiner Name** Sheet of 09799910-0034 4 Attorney Docket No. OTHER ITEMS - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the anticle (when appropriate), title of the T<sup>2</sup> Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials\* No.1 publisher, city and/or country where published. SOROKINA et al, "Cloning and Preliminary Characterization of a Calcium-binding Protein Closely Related to Nucleolin on the Apical Surface of Inner Medullary Collecting Duct Cells," J. Biol. Chem., 1999, pp. 27491-27496, Vol. 274. SRIVASTAVA et al., "Molecular Dissection of Nucleolin's Role in Growth and Cell 40 Proliferation: New Insights," Faseb. J., 1999, pp. 1911-1922, Vol. 13. SUTTON et al., "Initiation of Apoptosis by Granzyme B Requires Direct Cleavage of 41 Bid. But Not Direct Granzyme B-mediated Caspase Activation," J. Exp. Med., 2000, pp. 1403-1413, Vol. 192. 42 THORNBERRY et al., "Caspases: Enemies Within," Science, 1998, pp. 1312-1316. Vol. 281. TORMANEN et al., "Enhanced Apoptosis Predicts Shortened Survival in Non-Small 43 Cell Lung Carcinoma," Cancer Res., 1995, pp. 5595-5602, Vol. 55. 44 TUTEJA et al., "Nucleolin: A Multifunctional Major Nucleolar Phosphoprotein," Crit. Rev. Biochem. Mol. Biol., 1998, pp. 407-436, Vol. 33. WYLLIE et al., "Cell Death: The Significance of Apoptosis," Int. Rev. Cytol., 1980. 45

Examiner	Date	
Signature	Considered	

XU et al., "Inhibition of DNA Replication and Induction of S Phase Cell Cycle Arrest

by G-Rich Oligonucleotides," J. Biol. Chem., 2001, pp. 43221-43230, Vol. 276.

pp. 251-306, Vol. 68.

46